

REMARKS

Claims 1-4, 9 and 10 are pending in this Application. By this Amendment, Applicants canceled Claims 1, 3, 4, 9 and 10, and added Claims 17-25. Consequently, Claims 17-25 are at issue.

Oath or Declaration

In paragraph 3, the Examiner rejected the oath or declaration as defective under CFR 1.67(a). Applicants submit a new declaration.

Arrangement of the Specification and Abstract

In paragraph 4, the Examiner provided guidelines for the preferred layout and content of the application. Applicant amended the specification to include appropriate headings to the application. In addition, in paragraph 5, the Examiner requests an Abstract of the disclosure to be submitted under 37 CFR 1.72(b). In accordance with this requirement the Applicants submit an Abstract on a separate sheet, which traverses this objection.

References

Two references crossed out on the Form 1449 have not been considered. Specifically, EP 0-585-552(A1) was submitted in the German language. Applicant submits Canadian Application No. CA 2,100,212 (A1), which is an English language equivalent of the German application. For the Norman *et al.* (1991) reference, the Examiner requested a legible copy. In accordance with this request, we enclose a legible copy of the reference.

35 U.S.C. §112 Rejections

In the Office Action, Claims 1-3, 9 and 10 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are also rejected under §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it

is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

Applicants respectfully submit, that in view of the amendments presented above, specifically the substitution of new claims, that this rejection is no longer applicable. The rejection appears to be based primarily on the use of the terms "at least" and "a molecule resulting from partial modification thereof or an allelic mutant thereof," as appearing in the claims as filed. The new claims do not include this language; therefore, Applicants respectfully submit that the §112 rejection is no longer applicable. Support for the new claims can be found throughout the specification.

35 U.S.C. §102 Rejections

In paragraphs 10 and 11 of the Office Action, the Examiner rejected claims 1-4 and 9 as being anticipated by pir62 Accession No. S03013. Applicants respectfully traverse this rejection.

In order for a reference to constitute a §102(b) bar to patentability, the reference must disclose each and every element of the claimed invention. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983). Applicants submit that their invention, as recited in the newly amended claims, is not disclosed in pir62 Accession No. S03013. Applicants acknowledge and noted in the prior art section of the description that the entire sequence of human complement factor H had been disclosed. The new claims, however, are specifically directed to a truncated recombinant factor H, and specifically the complement control protein modules 1-4, 1-5 or 1-6 of complement factor H, are claimed. Applicants have found and demonstrate that modules 1-4, 1-5 and 1-6 of the protein are surprisingly and unexpectedly potent in regulating the complement activation path (specification at page 4, 1st paragraph). In fact, the truncated recombinant factor H expressed in yeast is approximately 10-1000 fold more potent than the serum protein FHp155, and that this potency is to be found particularly in constructs representing complement control protein modules 1-6, 1-5 and 1-4. The prior art does not refer to such constructs, comprising CCP modules of factor H, for the inhibition of

complement activation. Because nowhere in the cited reference or in the prior art is it suggested that the truncated protein modules according to the present invention would provide enhanced cofactor activity as demonstrated by Applicants, Applicants' invention is novel on the basis of new and unexpected properties of specific factor H protein modules.

Conclusion

In view of the Amendments and Remarks, Applicants respectfully submit that Claims 17-26 are now in condition for allowance.

Respectfully submitted,

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